

§ 97.124

proposals covered by this policy the department or agency head may take into account, in addition to all other eligibility requirements and program criteria, factors such as whether the applicant has been subject to a termination or suspension under paragraph (a) of this section and whether the applicant or the person or persons who would direct or has have directed the scientific and technical aspects of an activity has have, in the judgment of the department or agency head, materially failed to discharge responsibility for the protection of the rights and welfare of human subjects (whether or not the research was subject to federal regulation).

(Authority: 5 U.S.C. 301; 20 U.S.C. 1221e-3, 3474; and 42 U.S.C. 300v-1(b))

§ 97.124 Conditions.

With respect to any research project or any class of research projects the department or agency head may impose additional conditions prior to or at the time of approval when in the judgment of the department or agency head additional conditions are necessary for the protection of human subjects.

(Authority: 5 U.S.C. 301; 20 U.S.C. 1221e-3, 3474; and 42 U.S.C. 300v-1(b))

Subparts B-C [Reserved]

Subpart D—Additional ED Protections for Children Who Are Subjects in Research

SOURCE: 62 FR 63221, Nov. 26, 1997, unless otherwise noted.

§ 97.401 To what do these regulations apply?

(a) This subpart applies to all research involving children as subjects conducted or supported by the Department of Education.

(1) This subpart applies to research conducted by Department employees.

(2) This subpart applies to research conducted or supported by the Department of Education outside the United States, but in appropriate circumstances the Secretary may, under § 97.101(i), waive the applicability of some or all of the requirements of the

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regulations in this subpart for that research.

(b) Exemptions in § 97.101(b)(1) and (b)(3) through (b)(6) are applicable to this subpart. The exemption in § 97.101(b)(2) regarding educational tests is also applicable to this subpart. The exemption in § 97.101(b)(2) for research involving survey or interview procedures or observations of public behavior does not apply to research covered by this subpart, except for research involving observation of public behavior when the investigator or investigators do not participate in the activities being observed.

(c) The exceptions, additions, and provisions for waiver as they appear in § 97.101(c) through (i) are applicable to this subpart.

(Authority: 5 U.S.C. 301; 20 U.S.C. 1221e-3, 3474; and 42 U.S.C. 300v-1(b)).

§ 97.402 Definitions.

The definitions in § 97.102 apply to this subpart. In addition, the following definitions also apply to this subpart:

(a) *Children* are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

(b) *Assent* means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

(c) *Permission* means the agreement of parent(s) or guardian to the participation of their child or ward in research.

(d) *Parent* means a child's biological or adoptive parent.

(e) *Guardian* means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

(Authority: 5 U.S.C. 301; 20 U.S.C. 1221e-3, 3474; and 42 U.S.C. 300v-1(b)).

§ 97.403 IRB duties.

In addition to other responsibilities assigned to IRBs under this part, each IRB shall review research covered by this subpart and approve only research